Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029) – mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
LISA HYDE and MARK HYDE, a married couple, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFFS' MOTION *IN LIMINE #2* TO EXCLUDE OR LIMIT ARGUMENT AND EVIDENCE REGARDING THE SURGEON GENERAL'S CALL TO ACTION** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

MEMORANDUM OF LAW IN SUPPORT

I. Surgeon General's Message Misleads the Jury to Believe the U.S. Government Endorsed Bard's Conduct and the Necessity of IVC filters.

In opening statements for the *Booker* and *Jones* trials, Bard belabored the 2008 Surgeon General's call to action (the "Message"), using the U.S. government's imprimatur to show support for Bard's filters. In *Jones*, Bard described the call to action as follows[1]:

> Each year due to DVT, approximately two million of our fellow citizens are affected. Up to 600,000 people a year are hospitalized. And doctors and experts estimate that as many as 2- to 300,000 people die from pulmonary emboli caused by deep vein thrombosis every year…And I have always been

[1] Similar statement was made during the opening in the *Booker* trial. *See* Ex. A., Booker Trial Tr. 03/14/18 at 165:7-167:11.

> shocked by this statistic: DVT-related pulmonary embolism is the leading cause of preventable hospital deaths in United States hospitals. It is a serious issue, an issue that the medical community and the government recognizes.
>
> In 2008, the United States Surgeon General issued a call to arms… They noted the seriousness of the disease. They noted that it causes more deaths in this country each year than breast cancer, than AIDS, or even motor vehicle accidents...And they also recognized that inferior vena cava filters, like the Eclipse Filter, are an appropriate method of treating this disease in a number of patients. And it is to treat that disease, that life-threatening disease, that the men and women of Bard developed retrievable inferior vena cava filters…[2]

Bard's trial strategy is to inform the jury that Bard acted at the direction of the Surgeon General and the Surgeon General considers Bard's IVC filters necessary "to treat that disease, that life-threatening disease." This is unduly prejudicial and misleading. Fed. R. Evid. 403. In *Booker*, Defendants introduced exhibit 7411, through their expert Dr. Christopher Morris, and Chad Modra, V.P. of Regulatory Affairs in the *Booker* and *Jones* trials, respectively.[3] Both testified as to their opinions and impressions of the seriousness of the problem with which, Bard argues, the Message supported.[4] Bard asked Dr. Morris about the standard treatment for PE, he responded that it was anticoagulation and IVC filters; misleading jurors to believe the government sides with Bard.[5] Unless this *in limine* motion is granted, Bard will continue to imply to Plaintiffs' prejudice that the U.S. Surgeon General supports Bard and its IVC filters.

II. The Surgeon General's Message is Irrelevant, Confusing, and Any Probative Value Is Substantially Outweighed by the Danger of Unfair Prejudice.

For admission of governmental administrative findings, the Seventh Circuit "retains significant discretion as to whether such material ought to be admitted." *Young v. James Green Mgmt., Inc.*, 327 F.3d 616, 624 (7th Cir. 2003) (citing *Halloway v. Milwaukee*

---

[2] Ex. B, *Jones* Trial Tr. 05/15/18 at177:19-178:18. The opening further states, "But the FDA also noted that pulmonary embolism is a serious clinical issue, just like the Surgeon General did more recently. And they concluded that given the potential benefits, the risk of illness or injury presented by these devices is not unreasonable. In other words, the risks are outweighed by the benefits." *Id.* 196:8-13.

[3] Ex. D, *Jones* Trial Tr. 05/30/18 at 2310:2-2311:12.

[4] Ex. C, *Booker* Trial Tr. 03/27/18 at 2055:3-9; *See also*, Ex. B, *Jones* Trial Tr. 04/30/18 at 2310:2-7; 2311:8-12.

[5] Ex. C, *Booker* Trial Tr. 03/27/18 at 2052:15-2055:2.

County, 180 F.3d 820, 827 n. 9 (7th Cir. 1999).[6] It is unfair to allow one party to buttress factual contentions about safety by "using the imprimatur of the Surgeon General of the United States." *Philip Morris USA, Inc. v. Pollari*, 228 So. 3d 115, 130 (Fla. Ct. App. 2017).[7] Suggesting to the jury that the government supported Bard's conduct to alleviate a "fatal medical problem" as Bard describes in it's opening statement slides is unfairly prejudicial as it improperly infers to the jury that federal government's action "absolved the defendants from liability for negligence." *Gruca v. Alpha Therapeutic Corp.*, 51 F.3d 638, 645 (7th Cir. 1995)(citing *Davis v. FMC Corp., Food Processing Mach. Div*., 771 F.2d 224, 233 (7th Cir. 1985))[8]. Plaintiffs urge the same conclusion. Fed. R. Evid. 403.

III. The Surgeon General's Message is Inadmissible Hearsay.

In *Pollari*, Surgeon General messages were deemed "hearsay because they consisted of multiple levels of out-of-court statements" not testifying at trial and "offered to prove their truth." *Pollari*, 228 So. 3d at 120. Third-party statements "do not become admissible for their truth by virtue of their presence in a public record and instead must have an independent basis for admissibility." *Jordan v. Binns*, 712 F.3d 1123, 1133 (7th Cir. 2013). Also, the Message is not a public record under the office activities category because it is not a record or report of the activities of the Surgeon General's Office. *See Pollari* 228 So. 3d at 121; Fed. R. Evid. 803(8).[9] The second and third categories of 803(8)(A) do not

---

[6] A district court "must always determine whether the prejudicial effect of admitting such unreliable information may outweigh its probative value and thereby render it inadmissible under Fed. R. Evid. 403." *Young*, 327 F.3d at 624 (cit. om.).

[7] The *Pollari* decision found Surgeon General messages inadmissible and concluded it was a harmful error to admit them.

[8] Whether the FDA was negligent in its regulation of fractionators was not an issue before the jury. By directing the jury's attention to the FDA's regulatory role and away from the defendants' own conduct, Alpha suggested that the FDA's actions absolved the defendants from liability for negligence. Such an argument is impermissible.

[9] The third prong did not apply in *Pollari*, because it was decided under Florida law, and Plaintiff does not cite the decision as to the third prong.

apply.[10] The Message does not qualify for the public records hearsay exception.[11]

IV. Wisconsin Utilizes the Consumer Expectation Test, Not Risk/Benefit Analysis

Additionally, the Message is not applicable in the *Hyde* case since the only relevance for its admission is for Bard to bolster the benefit side of a risk/benefit analysis.[12] Section 895.047(b) of the Wisconsin Statutes requires that any alleged defective condition render product unreasonably dangerous. In Wisconsin, a product is unreasonably dangerous "where it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer." *Green v. Smith & Nephew AHP, Inc.*, 245 Wis.2d 772, 825-26 (Wis. 2001).[13] Even if there is perceived uncertainty as to whether the consumer expectations test is the law in Wisconsin, a consumer's expectations are most certainly a factor.[14] Therefore, there is no relevance to the Message in the context of the law applicable to Mrs. Hyde's case because as a fact supporting the purported benefits versus risks, it is not relevant; under a consumer expectation/contemplation test it does not make any consequential fact more or less probable in determining the ultimate issues. Fed. R. Evid. 401, 402.

---

[10] Fed. R. Evid. 803(8)(A)(i) does not apply; the Message was not based on a public official's first-hand observation of events. Nor does Fed. R. Evid. 803(8)(A)(ii) apply; the Message at-issue represents consensus opinions from a 2006 workshop not factual findings in an investigation. 803(8)(B) also does not apply because the message was a result of a workshop; it lacks trustworthiness.

[11] In *Booker*, Plaintiffs objected based on hearsay and then lack of foundation for the public record exception. Objections overruled. *See* Ex. A, *Booker* Trial Tr. 03/27/18 at 2053:3-25. In *Jones*, Plaintiffs objected under 803.18 and lack of foundation. Objection was overruled on foundation and deemed admissible under 803.8, public records exception. Ex. Ex. D, *Jones* Trial Tr. 05/30/18 at 2310:12-17.

[12] Ex. B, at 196:8-13 (quoted *supra*, fn. 2).

[13] Wisconsin's product liability law is a statutory scheme, enacted in 2011. *Forsythe v. Indian River Transp. Co.*, 344 Wis. 2d 520 (Wis. Ct. App. 2012). Common law is not superseded by the 2011 enacted statutory scheme. "Wisconsin's 2011 codification of its product liability law generally does not supersede the common law." *Janusz v. Symmetry Med. Inc.*, 256 F. Supp. 3d 995, 1000–01 (E.D. Wis. 2017).

[14] *In re Zimmer Nexgen Knee Implant Products Liab. Litig.*, 218 F. Supp. 3d 700, 723 (N.D. Ill. 2016), *aff'd sub nom. In re Zimmer, NexGen Knee Implant Products Liab. Litig.*, 884 F.3d 746 (7th Cir. 2018)(citing *Green v. Smith & Nephew AHP, Inc.*, 245 Wis.2d 772, 826, 629 N.W.2d 727, 752 (2001))

RESPECTFULLY SUBMITTED this 10th day of August 2018.

GALLAGHER & KENNEDY, P.A.

By: */s/ Mark O'Connor*

Mark S. O'Connor
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of August 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine